WHAT IS CLAIMED IS:

1. A method for determining an expression level of a target protein in a biological sample comprising a cell, comprising:

(a) immunohistochemically staining cells in the sample and at least a first control cell pellet and a second control cell pellet using a detectably-labeled antibody directed against the target protein, wherein the expression level of the target protein in the first and the second control cell pellets is known, and wherein the expression level of the target protein in the first and second control cell pellets is not the same,

(b) determining the optical density of the stained cells in the sample and the first and second control cell pellets stained as in step (a),

(c) generating a calibration curve relating optical density of the stained first and second control cell pellets with the known amounts of the target proteins in the cells of said cell pellets; and

(d) determining the expression level of the target protein in the cells in the biological sample by relating the optical density of the stained cells in the sample to the amount of the target protein using the calibration curve generated in step (c).

2. The method of claim 1, wherein the target protein is a protein that is specifically expressed in malignant cells in an animal.

3. The method of claim 2, wherein the target protein is HER-2/*neu*, HER-3, HER-4, estrogen receptor, prostate-specific antigen, EGFR, AKT, p13 kinase and MAP kinase.

4. The method of claim 1, wherein the cell pellets are prepared from cultured cell lines.

5. The method of claim 4, wherein the cultured cell line expresses a consistent amount of the target protein.

6. The method of claim 1, wherein the amount of target protein in the cell pellets is determined immunohistochemically.

7. The method of claim 6, wherein the amount of target protein is determined by ELISA assay.

8. The method of claim 1, wherein the amount of target protein is normalized to the amount of protein in the cell pellet.

9. The method of claim 8, wherein the amount of target protein is normalized to the amount of target protein per cell.

10. The method of claim 8, wherein the amount of target protein in the calibration curve is expressed as number of molecules per cell.

11. The method of claim 1, wherein the optical density of staining in the cells of the biological sample is determined using image analysis.

12. The method of claim 11, wherein image analysis is performed by splitting a signal comprising the optical density of the stained biological sample into a multiplicity of signals that are processed using optical filters having different absorption and transmittance properties, so that each signal is specific for one of a multiplicity of stains used to stain the cells in the biological sample.

13. The method of claim 1, wherein the detectable label is a chromagen or a fluorophore.

14. The method of claim 1, wherein the expression level of the target protein in the first and second cell pellet is determined by ELISA.